K072357

SEP 1 8 2007

Special 510(k) Summary
for
NewTom VG Computed Tomography X-Ray System

1. SPONSOR

AFP Imaging Corporation
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Date Prepared: August 21, 2007

2. DEVICE NAME

Proprietary Name:	NewTom VG Computed Tomography X-Ray System
Common/Usual Name:	X-Ray System
Classification Name:	Computed Tomography X-Ray System

3. PREDICATE DEVICES

NewTom 3G Computed Tomography X-Ray System K041137

4. DEVICE DESCRIPTION

The NewTom VG Computed Tomography X-Ray System (NewTom VG) is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images. It then reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of such volume, displaying both two- and three-dimensional images. The NewTom VG can measure distances and thickness on two-dimensional images. Such images can be printed or exported on magnetic and optical media.

The NewTom VG is designed for use in diagnostic support both in dento-maxillo-facial radiology, with a particular reference to "planning" and to monitoring of implantations, and in the field of maxillofacial surgery.

The NewTom VG hardware, including a scanner unit (comprised of an X-ray source, flat panel detector and a motorized arm) and a control box, facilitates the acquisition of a full X-ray sequence by the device software. The NewTom VG software runs on an x86 architecture based workstation. The NewTom VG reconstructs a three-dimensional model of x-ray images similar to the three-dimensional model obtained using the parent NewTom 3G Computed Tomography X-Ray System (NewTom 3G).

5. INTENDED USE

The NewTom VG is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The NewTom VG accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the NewTom Computed Tomography X-ray System and the parent NewTom 3G Computed Tomography X-ray Systems are substantially equivalent in that they are devices designed to provide images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The proposed NewTom VG and the parent NewTom 3G are computer controlled dedicated x-ray imaging devices that construct three-dimensional models from images taken during a rotational x-ray sequence. It is optimized for bone morphology analysis of the maxillofacial region.

The proposed NewTom VG and the NewTom 3G both use an X-ray imaging system that acquires a 360 degrees rotational x-ray sequence and reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of this volume, displaying both two- and three-dimensional images.

The proposed NewTom VG hardware, including a control box and framework comprised of an x-ray source, detector and either a fixed or rotating arm whereas the NewTom 3G system consists of the same components with only a fixed arm. The

proposed NewTom VG allows imaging to be performed in both a sitting and standing position and the parent NewTom 3G system only allows imaging to be performed in a supine position. The above differences do not impact safety or effectiveness since both the parent NewTom 3G and the proposed NewTom VG system are identical in that they are computer controlled dedicated x-ray imaging devices that constructs three-dimensional models from images taken during a rotational x-ray sequence. The technological characteristics for both the proposed NewTom VG and the parent NewTom 3G devices provide the user with a method of constructing a three-dimensional models from images taken during a rotational x-ray sequence. Therefore, the addition of hardware to improve image quality and flexibility of design represent minor technological differences that do not affect the overall safety or effectiveness of the proposed NewTom VG Computed Tomography X-ray System.

7. Performance Testing

Electrical safety, EMC/EMI testing, and verification and validation testing were performed to support the hardware and software modifications. The NewTom VG Computed Tomography X-Ray System met all requirements, and functioned as intended and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 18 2007

AFP Imaging Corporation
% Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K072357
Trade/Device Name: NewTom VG Computer Tomography X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 21, 2007
Received: August 22, 2007

Dear Ms. McNamra-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: NewTom VG Computed Tomography X-ray System

Indications for Use:

The NewTom VG Computed Tomography X-ray System is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery.

The NewTom VG accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two-dimensional images and three-dimensional renderings.

Prescription Use __X__ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072357